

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CENTRAL DIVISION**

LORI NICHOLSON; and WILLIS
WILLIAM NICHOLSON,

Plaintiffs,

vs.

BIOMET, INC; BIOMET
ORTHOPEDICS, LLC; BIOMET
MANUFACTURING CORP; and
BIOMET US RECONSTRUCTION
LLC,

Defendants.

No. 18-cv-3057-CJW-KEM

ORDER

This matter is before the Court on Lori Nicholson and Willis William Nicholson's ("plaintiffs") Motion to Strike Certain Affirmative Defenses. (Docs. 13-14). Defendants, together, filed their resistance (Doc. 243), and defendants subsequently supplemented their resistance (Doc. 244). The Court considers this motion fully ripe. For the following reasons, plaintiffs' motion is **granted in part; denied in part**; and **denied as moot** as to affirmative defenses two, three, seventeen, twenty-five, thirty-nine, forty-two, as to affirmative defense seven to the extent the affirmative defense relies upon Section 19 of the *Restatement (Third) of Torts: Products Liability*, and as to affirmative defense eighteen as the affirmative defense relates to informed consent, release, and waiver. To the extent defendants have moved for leave to amend their thirty-fourth and thirty-eighth affirmative defenses, such motion is **denied**.

I. BACKGROUND

This case is one of a series of products liability cases, some of which the Judicial Panel on Multidistrict Litigation assigned to the Northern District of Indiana for consolidated and coordinated pretrial proceedings. (Doc. 215, at 1). Pursuant to an order entered by the Northern District of Indiana, plaintiffs filed their complaint in that court, but pled that venue was proper in the Northern District of Iowa. (*Id.*, at 2; Doc. 1, at 3). The Court will not presently address whether venue in this Court is proper beyond noting that defendants have pled as an affirmative defense that “venue is improper.”¹ (Doc. 8, at 55).

In sum, plaintiffs brought this action on a products liability theory, arguing that an artificial hip joint allegedly manufactured and marketed by defendants was defective, and that the allegedly defective hip joint was implanted into plaintiff Lori Nicholson. (Doc. 1). As a result of the joint’s alleged defects, plaintiffs claim that plaintiff Lori Nicholson had to undergo painful and risky corrective surgery and that plaintiffs suffered damages as a result of the defects. (*Id.*). Defendants responded to plaintiffs’ complaint with forty-two affirmative defenses, twenty-three of which plaintiffs seek to have stricken. (Docs. 8, at 49-57; 13, at 1-4). Of those twenty-three affirmative defenses, defendants have agreed to withdraw five in full and two in part.² (Doc. 243, at 24). The

¹ The affirmative defense reads, in full: “Plaintiffs filed this Complaint in an improper forum, and therefore, venue is improper.” (Doc. 8, at 55). The Court is not able to say, with certainty, whether the improper forum to which defendants refer is the Northern District of Indiana, where the complaint was filed, or the Northern District of Iowa, to which the parties likely understood this action would eventually be transferred.

² Consistent with defendants’ representations, the Court will consider affirmative defenses two, three, seventeen, twenty-five, thirty-nine, and forty-two to be withdrawn in full, affirmative defense seven withdrawn “to the extent it relies upon Section 19 of the *Restatement (Third) of Torts: Products Liability*,” and affirmative defense eighteen withdrawn “as it relates to informed consent, release, and waiver.” (Doc. 243, at 24).

eighteen affirmative defenses that remain at issue are as follows: one, seven (in part), eight, nine, fifteen, eighteen (in part), nineteen, twenty-one, twenty-two, twenty-six, twenty-seven, twenty-eight, thirty-two, thirty-four, thirty-six, thirty-seven, and thirty-eight.

II. APPLICABLE LAW

Plaintiffs bring their motion under Federal Rule of Civil Procedure 12(f), which permits a court to “strike from a pleading an insufficient defense . . .” Rule 8(c) states that “a party must affirmatively state any . . . affirmative defense.” “The [Federal Rules of Civil Procedure] do not require a party to plead every step of legal reasoning that may be raised in support of [an] affirmative defense; they only require a defendant to state in short and plain terms its defenses to a plaintiff’s claims.”³ *U.S. Commodity Futures Trading Comm’n v. U.S. Bank, N.A.*, No. 13-CV-2041-LRR, 2014 WL 294219, at *9 (N.D. Iowa Jan. 27, 2014) (quoting *Wisland v. Admiral Beverage Corp.*, 119 F.3d 733, 737 (8th Cir. 1997)).

The requirement that an affirmative defense be pled in short and plain terms is intended to give the opposing party notice of the affirmative defense and an opportunity to refute the defense. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971); *see also First Union Nat’l Bank v. Pictet Overseas Tr. Corp.*, 477 F.3d 616, 622 (8th Cir. 2007) (“The Supreme Court has indicated that the Rule 8(c) pleading

³ In considering motions to strike affirmative defenses, this Court has previously engaged in a discussion of whether the pleading standards established in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), apply to affirmative defenses. *See, e.g., U.S. Bank*, 2014 WL 294219, at *9-10; *FDIC v. Dosland*, 298 F.R.D. 388, 393-94 (N.D. Iowa 2013). In its prior discussions of this issue, the Court has reached the conclusion that whether *Twombly* and *Iqbal* apply to affirmative defenses remains unanswered. *U.S. Bank*, 2014 WL 294219, at *9-10; *Dosland*, 298 F.R.D. at 393-94. Plaintiffs have not asked the Court to apply the *Twombly/Iqbal* standard to defendants’ affirmative defenses, and the Court therefore finds it unnecessary to address whether the heightened pleading standard established under *Twombly* and *Iqbal* applies to affirmative defenses.

requirement is intended to give the opposing party both notice of the affirmative defense and an opportunity to rebut it.” (citations omitted)). The Eighth Circuit Court of Appeals has, therefore, liberally interpreted affirmative defenses in determining whether such defenses have been adequately pled and has held that “when an affirmative defense is raised in the trial court in a manner that does not result in unfair surprise, technical failure to comply with Rule 8(c) is not fatal.” *Pictet*, 477 F.3d at 622 (alterations, citations, and internal quotation marks omitted). “Nowhere in Rule 8(c) is there a requirement for the party pleading an affirmative defense to show that the pleader is entitled to relief, or, in the case of a defendant, that the affirmative defense, if the facts articulated were true, absolves the pleader of liability.” *U.S. Bank*, 2014 WL 294219, at *10 (alteration and internal quotation marks omitted).

When striking a pleading under Rule 12(f), a district court enjoys broad discretion. *Stanbury Law Firm v. IRS*, 221 F.3d 1059, 1063 (8th Cir. 2000) (citations omitted). “Despite this broad discretion[,], however, striking a party’s pleadings is an extreme measure, and, as a result, . . . motions to strike under [Federal Rule of Civil Procedure 12(f)] are viewed with disfavor and are infrequently granted.” *Id.* (alteration, citations, and internal quotation marks omitted). “A motion to strike a defense will be denied if the defense is sufficient as a matter of law or if it fairly presents a question of law or fact which the court ought to hear.” *Lunsford v. United States*, 570 F.2d 221, 229 (8th Cir. 1977) (citation and internal quotation marks omitted). If, however, an affirmative defense “is foreclosed by prior controlling decisions or statutes,” the district court may properly strike the defense as legally insufficient. *Liguria Foods, Inc. v. Griffith Labs., Inc.*, No. C14-3041-MWB, 2014 WL 6066050, at *2 (N.D. Iowa Nov. 13, 2014) (citing *United States v. Dico, Inc.*, 266 F.3d 864, 879-80 (8th Cir. 2001)). In determining the substantive issue of whether an affirmative defense is legally sufficient, a court sitting in diversity must apply state law. *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415,

427 (1996). With respect to procedural issues, however, a court sitting in diversity must apply federal law. *Id.*

III. DISCUSSION

In considering whether to strike each affirmative defense, the Court will consider only those arguments that plaintiffs have asserted with respect to each individual affirmative defense. Both parties apply Iowa law in arguing substantive legal issues, and, for purposes of this motion, the Court will therefore consider Iowa law to govern those substantive legal issues that may arise.

A. First Affirmative Defense

Defendants' first affirmative defense asserts "fail[ure] to state a claim against [d]efendants upon which relief may be granted." (Doc. 8, at 49). In support of their motion to strike this affirmative defense, plaintiffs state that "[l]egal insufficiency is not a proper affirmative defense under [Federal Rule of Civil Procedure] 8(c)." (Doc. 14, at 10). The Eighth Circuit Court of Appeals has stated as follows: "Pursuant to [Federal Rule of Civil Procedure 12(b)], the defense of failure to state a claim upon which relief can be granted may be asserted, at the option of the pleader, either in the pleader's answer or in a pre-answer motion." *Madewell v. Downs*, 68 F.3d 1030, 1048 n.21 (8th Cir. 1995). The Eighth Circuit went on to characterize such a defense as an "affirmative defense" when raised in an answer. *Id.* Defendants brought the defense of failure to state a claim upon which relief may be granted in their answer, which, in the Eighth Circuit, is permissible. Plaintiffs' motion to strike is therefore **denied** as to defendants' first affirmative defense.

B. Seventh (In Part), Eighth, and Thirty-Sixth Affirmative Defenses

To the extent defendants have not withdrawn their seventh affirmative defense, the defense asserts that "[p]laintiffs' claims are barred, in whole or in part, by the principles set forth in the *Restatement (Third) of Torts: Product[s] Liability*, including . . . Section

4, Section 6 (including . . . §§ 6(c), and comment f) . . . and the comments thereto.” (Doc. 8, at 50). Defendants’ eighth affirmative defense asserts that “[p]laintiffs’ claims are barred, in whole or in part, by the principles set forth in the *Restatement (Second) of Torts* Section 388, Comment n and/or similar doctrines and principles contained in the *Restatement (Third) of Torts: Products Liability*.” (*Id.*, at 51). Defendants’ thirty-sixth affirmative defense states “[p]laintiffs’ warranty-based claims are barred, in whole or in part, by [p]laintiffs’ failure to satisfy all conditions precedent or subsequent to the enforcement of any such alleged warranties.” (Doc. 8, at 57).

Plaintiffs move to strike the seventh affirmative defense and part of the eighth affirmative defense because, plaintiffs claim, the defenses are “conclusory and devoid of any factual support or context.” (Doc. 14, at 11). Plaintiffs do not elaborate on their assertion that the defenses are insufficient. Further, although plaintiff requests that the Court strike “part of [defendants’] eighth affirmative defense[],” plaintiffs do not specify which part of the eighth affirmative defense plaintiffs want stricken. (*Id.*). With respect to the thirty-sixth affirmative defense, plaintiffs argue that the defense should be stricken because defendants “fail to mention which conditions precedent or subsequent were not met.” (*Id.*, at 15).

In resisting plaintiffs’ motion, defendants explain why they believe the seventh affirmative defense, in relevant part, should not be stricken. (Doc. 243, at 8-11). Defendants specifically identify which portions of Sections Four, Six, and the Comments defendants contend are at issue, and defendants apply the facts of this case to the *Restatement* to further explain the applicability of the Sections. (*See id.*, at 8-11). Likewise, defendants detail their theory of how Section 388 of the *Restatement (Second) of Torts*, as pled in the eighth affirmative defense, applies to the instant case, and defendants offer tailored assertions on how defendants intend to rely on Section 388 in defending this case. (*See id.*, at 11-12). Defendants fail, however, to even mention the

“similar doctrines and principles contained in the *Restatement (Third) of Torts: Products Liability*” to which the eighth affirmative defense alludes. (*See id.*; Doc. 8, at 51).

Finally, with respect to their thirty-sixth affirmative defense, defendants explain their theory of how Iowa state law may impose conditions precedent on plaintiffs’ warranty claims, defendants set forth the specific code provision upon which their theory is based, and defendants’ resistance states that the defects of which plaintiffs allegedly should have provided defendants notice are those defects of which plaintiffs now complain. (Doc. 243, at 22).

The Eighth Circuit has held that so long as a party raises its affirmative defenses “in a manner that does not result in unfair surprise,” the affirmative defenses need not be stricken as a matter of course. *Pictet*, 477 F.3d at 623 (citations and internal quotation marks omitted). In *First Union National Bank v. Pictet Overseas Trust Corp.*, the Eighth Circuit allowed an affirmative defense to stand where the defense was not properly pled, but the party relying on the defense made known its intent to rely on the defense by detailing the applicability of the defense in the party’s briefs. *Id.* at 622-23. The Eighth Circuit so held because by the time summary judgment briefing was submitted, the party attempting to defeat the defense had known of the defense for more than one year, which, the Eighth Circuit determined, was “certainly a long enough period to preclude a claim of surprise.” *Id.* at 623 (citations omitted).

Without reaching the issue of whether the seventh, eighth, and thirty-sixth affirmative defenses were properly pled in defendants’ answer, the Court finds that the seventh affirmative defense, in relevant part, and the thirty-sixth affirmative defense have been detailed in defendants’ resistance to the instant motion to such a degree that plaintiffs will not be able to credibly claim “unfair surprise” by the time the parties are due to submit their dispositive motions. Likewise, the eighth affirmative defense is detailed as to Section 388. The eighth affirmative defense is not explained, however, to the extent

defendants purport to rely on “similar doctrines and principles contained in the *Restatement (Third) of Torts: Products Liability*.” (Doc. 8, at 51). Averring a general reliance on an entire *Restatement*, essentially to the extent the *Restatement* benefits the pleading party, is not sufficient to put an opposing party on notice as to what is being pled. That is, defendants cannot assert a general reliance upon the *Restatement (Third) of Torts: Products Liability* and expect plaintiffs—or the Court—to infer which Sections defendants intend to rely on. As such, the Court finds that the eighth affirmative defense has not been pled sufficiently to survive plaintiffs’ motion to the extent the defense relies on “similar doctrines and principles contained in the *Restatement (Third) of Torts: Products Liability*.” (Doc. 8, at 51).

By the time dispositive motions are due, plaintiffs will have had access to defendants’ resistance to the instant motion for approximately seven months. (*See* Docs. 239, 243). The Court finds that this is sufficient time for plaintiffs to prepare a response to the affirmative defenses, to the extent the defenses were discussed in defendants’ resistance. Moreover, even as of the filing of this Order, discovery has yet to conclude and, indeed, will remain open for approximately four months, which gives plaintiffs time to further investigate the defenses. Plaintiffs’ motion is therefore **denied** as to the seventh affirmative defense, to the extent the seventh affirmative defense has not been withdrawn, **denied** as to the portion of the eighth affirmative defense that relies on “the principles set forth in the *Restatement (Second) of Torts* Section 388, comment n,” **granted** as to the portion of the eighth affirmative defense that purports to rely on “similar doctrines and principles contained in the *Restatement (Third) of Torts: Products Liability*,” (*see* Doc. 8, at 51), and **denied** as to the thirty-sixth affirmative defense.

C. Ninth, Twenty-First, and Twenty-Second, Thirty-Fourth, and Thirty-Eighth Affirmative Defenses

Plaintiffs argue that each of the following affirmative defenses, as pled, is vague and conclusory and should, therefore, be stricken:

Ninth affirmative defense: Plaintiffs' claims are barred, in whole or in part, by [d]efendants' compliance with the state of the art, industry standards, and/or applicable government statutes and regulations. (*Id.*).

Twenty-first affirmative defense: In the event that it is determined that [p]laintiffs are entitled to recover against [d]efendants, [p]laintiffs' recovery should be reduced in proportion to the degree or percentage of negligence, fault, or exposure to products attributable to [p]laintiffs or others, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom [p]laintiffs have settled or may settle in the future. (*Id.*, at 53).

Twenty-second affirmative defense: To the extent applicable, [d]efendants are entitled to contribution from any person and/or entity whose negligence or other fault contributed to [p]laintiffs' alleged injuries and damages. (*Id.*, at 53).

Thirty-fourth affirmative defense: Plaintiffs' claims are barred, in whole or in part, because [d]efendants are entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute whose substantive law controls the action. (*Id.*, at 56).

Thirty-eighth affirmative defense: Plaintiffs' claims are barred, in whole or in part, by the statutory safe-harbors and/or other provisions in consumer protection and deceptive trade practice laws. (*Id.*, at 57).

Plaintiffs have not substantiated their assertion that the twenty-first and twenty-second affirmative defenses are vague and conclusory, and the Court does not view them as such. (*See* Doc. 14, at 13 (asserting, in subheading, that "Defendants' Twenty-First and Twenty-Second Affirmative Defenses Are Vague and Conclusory")). In pleading the twenty-first and twenty-second affirmative defenses, defendants have put plaintiffs on

notice that defendants intend to rely on a theory of contribution in arguing the merits of the case and on a contributory negligence theory in assessing any damages that may ultimately be awarded. It is often through the discovery process that parties learn that the negligent actions of others may have led to a plaintiff's alleged injuries. As such, the Court does not expect defendants to be able to name, at the answering stage, those individuals or entities that allegedly acted negligently. To the extent plaintiffs object to the defenses because defendants have not specifically identified those individuals and/or entities upon which defendants intend to assert contribution, the Court rejects plaintiffs' argument.

In arguing that the ninth, thirty-fourth, and thirty-eighth affirmative defenses are vague and conclusory, plaintiffs seem to object to defendants' failure to identify the specific statutes that defendants intend to rely on in conjunction with the aforementioned affirmative defenses. In resisting plaintiffs' motion to strike, defendants identify each statute upon which defendants base the subject affirmative defenses. (Doc. 243, at 12-14, 21). As a result, any erroneous failure to identify the applicable statutes has been cured, and plaintiffs cannot later claim that reliance on such statutes would result in unfair surprise. *See Pictet*, 477 F.3d at 623. The Court reiterates that there is a substantial amount of time remaining between the filing of this Order and the deadline for the parties to file their dispositive motions, which counsels against striking the defenses. The Court therefore declines to strike the ninth, thirty-fourth, and thirty-eighth affirmative defenses based on plaintiffs' argument that the defenses are vague and conclusory. If defendants still wish to amend their thirty-fourth and thirty-eighth affirmative defenses (*see* Doc. 243, at 21), defendants are directed to seek leave to do so through any motions that may be proper. To the extent defendants have moved for leave to amend the thirty-fourth and thirty-eighth affirmative defenses, defendants' motion is **denied**.

Additionally, plaintiffs argue that the ninth, twenty-first, and twenty-second affirmative defenses are impermissible under Iowa law. (Doc. 14, at 11, 13). Plaintiffs are mistaken in their assertion that Iowa does not recognize the ninth affirmative defense. The Iowa Supreme Court has held that “the state of the art defense may be a complete defense in product defect cases, but only as to a claim other than a negligent failure to warn.”⁴ *Mercer v. Pittway Corp.*, 616 N.W.2d 602, 622 (Iowa 2000). To the extent plaintiffs’ claims are based on a theory other than defendants’ alleged negligent failure to warn, defendants’ state of the art defense, as asserted in the ninth affirmative defense, is a legally recognized defense.

As to the twenty-first and twenty-second affirmative defenses, plaintiffs are correct that fault can only be allocated to “a claimant, a person named as a defendant, a person released pursuant to a settlement, or a third-party defendant.” *Selchert v. Iowa*, 420 N.W.2d 816, 819 (Iowa 1988) (citing IOWA CODE § 668.2). Plaintiffs are incorrect, however, that the affirmative defenses at issue are framed in such a limited fashion as to seek to limit liability based on the contribution of *only* non-parties. Although non-parties are explicitly mentioned in the twenty-first affirmative defense and may be implicitly included in the twenty-second affirmative defense, many others from whom contribution may validly be sought are also included in the defenses. The Court therefore declines to strike the defenses in their entirety.

Plaintiffs’ argument in favor of striking the defenses concerns only defendants’ purported attempt to attribute fault to non-parties. (Doc. 14, at 13). Because the Iowa Supreme Court has held that fault may not be attributed to non-parties, the Court finds it

⁴ In asserting that “a defendant may not rely on a state of the art defense for failing to warn subsequent to learning of a product defect,” plaintiffs cite to and quote *Mercer v. Pittway Corp.* out of context. (Doc. 14, at 11). When the portion of *Mercer* that plaintiffs quote is read in context, *Mercer* is read as supporting a state of the art defense for some purposes but not others. See *Mercer*, 616 N.W.2d at 622.

proper to strike the twenty-first and twenty-second affirmative defenses, to the extent those defenses seek to attribute fault to non-parties. The Court will not address the attribution of fault to individuals or entities other than non-parties because plaintiffs have not raised an objection with respect to such attribution. Similarly, the Court will not address defendants' argument that defendants should be permitted to conduct discovery with respect to the twenty-second affirmative defense because defendants have not brought a proper discovery motion. (*See* Doc. 243, at 18).

With respect to the ninth, thirty-fourth, and thirty-eighth affirmative defenses, plaintiffs' motion to strike is **denied**. With respect to the twenty-first and twenty-second affirmative defenses, plaintiffs' motion to strike is **granted in part and denied in part**.

D. Fifteenth Affirmative Defense

Defendants' fifteenth affirmative defense states "[d]efendants have no legal relationship or privity with [p]laintiffs and owe no duty to plaintiffs by which liability could be attributed to it." (Doc. 8, at 52). Plaintiffs argue that the fifteenth affirmative defense fails as a matter of law and should be stricken because "[t]he privity defense in products liability actions is a relic long abolished." (Doc. 14, at 12). In response, defendants argue that even if the privity affirmative defense is not applicable to plaintiffs' strict products liability claims, the defense is applicable to plaintiffs' warranty claims. (Doc. 243, at 14-15).

The Court recognizes defendants' argument that the privity defense may be applicable to plaintiffs' warranty claims even if the defense is not applicable to the products liability claims. The Court, however, need only address the applicability of the affirmative defense to the products liability claims. Plaintiffs' claims do not sound in just products liability and breach of warranty. Rather, plaintiffs' claims also include negligence claims (counts five and nine), fraud claims (counts ten and eleven), and a loss of consortium claim (count thirteen). Plaintiffs' decision to address only the products

liability claims in bringing its motion to strike indicates that plaintiffs do not seek to strike the affirmative defense as to the warranty, negligence, fraud, and loss of consortium claims. Indeed, if plaintiff sought to strike the defense with respect to the aforementioned claims without offering any argument or legal support, such a pleading would likely be insufficient. The Court therefore finds it proper to construe plaintiffs' motion as seeking to strike the fifteenth affirmative defense with respect to only the products liability claims.

The Iowa Supreme Court has repeatedly held that privity is not a defense to products liability actions that are premised on negligence. *West v. Broderick & Bascom Rope Co.*, 197 N.W.2d 202, 209 (Iowa 1972); *State Farm Mut. Auto. Ins. Co. v. Anderson-Weber, Inc.*, 110 N.W.2d 449, 456 (Iowa 1961). As such, to the extent that plaintiffs' products liability claims are based on a theory of negligence, defendants' fifteenth affirmative defense is stricken. Plaintiffs have not brought legal authority purporting to show that the affirmative defense should be stricken as to the products liability claims, to the extent those claims are based on a knowledge theory, as opposed to a negligence theory. As such, the Court will not consider whether the privity affirmative defense should be stricken as to plaintiffs' products liability claims, to the extent those claims are based on a knowledge theory. Plaintiffs' motion to strike the fifteenth affirmative defense is **granted** as to plaintiffs' products liability claims, to the extent those claims are based on a negligence theory.

E. Eighteenth Affirmative Defense (In Part)

Defendants' eighteenth affirmative defense, to the extent it has not been withdrawn, pleads as follows: "Plaintiffs' claims are barred because [p]laintiffs were advised of the risks associated with the matters alleged in [p]laintiffs' Complaint and knowingly and voluntarily assumed them. Under the doctrine of assumption of . . . risk, . . . or comparative fault, this conduct bars, in whole or in part, the damages that [p]laintiffs seek to recover herein." (Doc. 8, at 52). Plaintiffs assert that the affirmative

defense should be stricken because “Iowa law does not provide for a separate assumption of risk defense apart from the Iowa Comparative Fault Statute.” (Doc. 14, at 12 (citations omitted)). In response, defendants argue that the affirmative defense complies with Iowa’s requirements for pleading assumption of risk because the assumption of risk defense is pled in conjunction with defendants’ contributory negligence defense, instead of each defense being pled as a separate affirmative defense. (Doc. 243, at 15-16).

In holding that “assumption of risk may not be pleaded or instructed upon as a separate defense in cases in which contributory negligence is an available defense under the Iowa Comparative Fault Act,” the Iowa Supreme Court determined that assumption of risk was not an available defense *at all* if a defendant may rely upon contributory negligence as a defense under the Iowa Comparative Fault Act. *Coker v. Abell-Howe Co.*, 491 N.W.2d 143, 147-48 (Iowa 1992). Defendants incorrectly read the Iowa Supreme Court’s holding to mean that assumption of risk and contributory negligence may both be pled in the same case, so long as the two defenses are contained within the same defensive assertion. The Iowa Supreme Court did not reach that holding. Instead, the Iowa Supreme Court held that to allow a defendant to rely on both assumption of risk and contributory negligence defenses would be duplicitous and could result in inconsistent decisions. *Id.* at 147. As such, the Iowa Supreme Court held that assumption of risk could not be relied upon as an affirmative defense where contributory negligence was available as a defense. *Id.* at 147-48. Neither plaintiffs nor defendants point out, however, that the Iowa Supreme Court also held that assumption of risk remains a valid defense where contributory negligence is not an available defense, such as in defense to strict products liability claims. *Id.* Likewise, neither party addresses those claims for which a contributory negligence defense is unavailable to defendants.

As set forth *supra*, plaintiffs plead a number of claims, several of which sound in products liability. The Court finds that the assumption of risk defense is available to

defendants as to the claims sounding in products liability and is not available as to the claims for which the contributory negligence defense is available. The Court declines to address, *sua sponte*, which claims defendants may defend against by relying on a contributory negligence defense. As to the eighteenth affirmative defense, plaintiffs' motion is **granted in part and denied in part** consistent with the Court's findings.

F. Nineteenth Affirmative Defense

Defendants' nineteenth affirmative defense states as follows: "At all relevant times herein, [p]laintiffs' physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the device." (Doc. 8, at 53). In moving to strike the affirmative defense, plaintiffs plead as follows: "To the extent that the sophisticated purchaser[] defense is the same as the learned intermediary defense, [the sophisticated purchaser defense] should be stricken for being redundant. To the extent that the sophisticated purchaser[] defense misstates the learned intermediary defense, it should be stricken as a matter of law." (Doc. 14, 12-13). Plaintiffs do not explain the basis for believing that the sophisticated purchaser defense, in this context, is the same as the learned intermediary defense, nor do plaintiffs explain how defendants allegedly misstate the learned intermediary defense.

The Court has been unable to find any Iowa state caselaw interpreting the learned intermediary doctrine as being redundant of the sophisticated purchaser doctrine. Indeed, the Court has been able to find little Iowa state caselaw interpreting the learned intermediary doctrine, which indicates not that the doctrine is necessarily invalid in Iowa, but rather that the Iowa state courts have not often interpreted the doctrine. Similarly, the Court is unable to ascertain the basis for plaintiffs' assertion that the affirmative defense may be a misstatement of the law. In the absence of plaintiffs offering argument regarding the alleged bases for striking the nineteenth affirmative defense, and in the absence of clear authoritative caselaw on the issues plaintiffs have raised, the Court is

persuaded that the nineteenth affirmative defense and plaintiffs' objections raised thereto "fairly present[] a question of law or fact which the court ought to hear." *Lunsford*, 570 F.2d at 229 (citation and internal quotation marks omitted). Plaintiffs' motion is therefore **denied** as to the nineteenth affirmative defense.

G. Twenty-Sixth, Twenty-Seventh, and Twenty-Eighth Affirmative Defenses

Plaintiffs argue that each of the following affirmative defenses is conclusory and, therefore, should be stricken:

Twenty-sixth affirmative defense: Plaintiffs' claims are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards, and regulations established, adopted, promulgated, or approved by any regulatory body with jurisdiction over the product, including but not limited to the United States, any state, and any agency thereof.

Twenty-seventh affirmative defense: Plaintiffs cannot show that any reasonable alternative design would have rendered the device to be safer overall under the *Restatement (Third) of Product[s] Liability* § 2, cmt. F, nor could [d]efendants have known of any alternative design that may be identified by [p]laintiffs.

Twenty-eighth affirmative defense: Plaintiffs' product liability causes of action are barred because the benefits of the device outweighed its risks.

(Doc. 8, at 54).

The Court is inclined to find that, in the context of this litigation, the twenty-seventh and twenty-eighth affirmative defenses have been set forth sufficiently to put plaintiffs on notice as to defendants' theories of defense. Even if the twenty-seventh and twenty-eighth affirmative defenses were deficient, however, any such deficiencies are resolved by defendants' resistance, in which defendants elaborate upon their defenses. Specifically, defendants explain that they intend to show that "there were no alternative safer designs available at the time of sale," and that the benefits of the hip implant

outweighed the risks of the implant's design. (Doc. 243, at 18-19). Plaintiffs have sufficient information regarding the twenty-seventh and twenty-eighth affirmative defenses such that plaintiffs will not be subject to unfair surprise if defendants later rely on the two defenses. *See Pictet*, 477 F.3d at 622. Plaintiffs' motion to strike is **denied** with respect to the twenty-seventh and twenty-eighth affirmative defenses.

Defendants have failed, however, to resist plaintiffs' motion to strike the twenty-sixth affirmative defense. Because defendants have not offered a resistance with respect to the twenty-sixth affirmative defense, defendants have not provided the same elaboration that defendants provided with respect to the twenty-seventh and twenty-eighth affirmative defenses. The twenty-sixth affirmative defense seeks to implicate the entire body of "applicable" statutory law and regulatory guidance at every jurisdictional level within the United States. (Doc. 8, at 54). Perhaps plaintiffs could devote sufficient resources to this case to determine which laws and regulatory guidance are applicable to "the manufacturing, labeling, packaging, and any advertising of the product," within the meaning of the twenty-sixth affirmative defense, but to do so, plaintiffs would be forced to develop the entirety of defendants' twenty-sixth affirmative defense with little guidance. (*Id.*). Defendants' decision to plead the twenty-sixth affirmative defense in such broad strokes without elaboration has deprived plaintiffs of "notice of the affirmative defense and an opportunity to rebut it." *Pictet*, 477 F.3d at 622 (citations omitted). The Court therefore finds it proper to **grant** plaintiffs' motion to strike the twenty-sixth affirmative defense.

H. Thirty-Second Affirmative Defense

Defendants' thirty-second affirmative defense states as follows: "Plaintiffs' claims are barred by the doctrine of implied preemption to the extent that they are premised on alleged misrepresentations or misstatements to the FDA. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)." (Doc. 8, at 55). Plaintiffs assert that

defendants' preemption defense fails as a matter of law because such a defense is unavailable for a device that has been classified as a Class II medical device by the Food and Drug Administration ("FDA"), such as the hip implant that is at issue in this case. (Doc. 13, at 14). In resisting plaintiffs' motion, defendants argue that plaintiffs' claims are preempted both expressly and impliedly. (Doc. 243, at 19-21). The thirty-second affirmative defense, however, pleads only implied preemption. The Court will, therefore, address only implied preemption.

The Court need not determine whether any or all of plaintiffs' claims are preempted by federal law. At this stage, the Court need only determine whether defendants' preemption affirmative defense is precluded as a matter of law. Again, the Court notes that it will consider only the arguments that the parties have raised; the Court will not scour the entire body of preemption law in an effort to consider even those arguments that the parties have not presented. Plaintiffs do not fully explain their argument that defendants cannot rely on a preemption defense, but to the best of the Court's understanding, plaintiffs assert that two cases that have been decided by the United States Supreme Court prevent defendants from setting forth a preemption defense.

The Court finds it helpful to first explain that under the Medical Devices Act, a medical device can be classified as a Class I, Class II, or Class III device, depending on the risks involved with the device. 21 U.S.C. § 360c(a). The FDA is responsible for classifying medical devices and approving medical devices for market entry. *Id.* § 360c(b). Class III devices go through the most rigorous level of review before they may be approved, Class II devices go through a less stringent review process, and Class I devices are subject to the lowest standard of review prior to approval. *Id.* § 360c(a). In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court considered whether the Medical Devices Act preempted certain state common law claims with respect to Class III devices. The Court answered that question in the affirmative, in

material part because of the stringent review process that Class III devices go through prior to being approved to enter the market. *Riegel*, 552 at 322-24.

The parties in the instant case agree that the hip implant at issue is a Class II device. (Docs. 13, at 14; 243, at 19-21). *Riegel* relied, in pertinent part, on the review process that is specific to Class III devices and did not explicitly opine on whether Class II devices may also be subject to implied preemption under the Medical Devices Act. Further, the Supreme Court did not affirmatively state that preemption could not exist absent the stringent review process that is specific to Class III devices. As a result, the Court cannot presently say, definitively, whether certain state common law claims are preempted with respect to Class II devices. The Court is satisfied, however, that the language of *Riegel* is not so strong and so broad as to preclude a litigant from advancing an argument that such claims are preempted with respect to Class II devices. That is, the Court finds that defendants' preemption affirmative defense is still colorable when considered in the posture of *Riegel*.

Plaintiffs also cite to *Buckman Co. v. Plaintiffs' Legal Committee*. The Court finds it likely that plaintiffs cite to *Buckman* simply because defendants cite to *Buckman* in their affirmative defense. Nevertheless, the Court will consider whether *Buckman* forecloses defendants' preemption affirmative defense. As with *Riegel*, *Buckman* addressed Class III devices and was decided largely based on the in-depth review process Class III devices must undergo prior to approval. *Buckman*, 531 U.S. 341, 350-52 (2001). Just as the Supreme Court determined in the more recent *Riegel* case, the *Buckman* Court determined that certain state common law claims are preempted by federal law. *Id.* Again, this Court is satisfied that in addressing Class III devices, the *Buckman* Court did not rule out the possibility of state law claims being preempted with respect to Class I and Class II devices.

The Court finds that neither *Riegel* nor *Buckman* precludes the possibility of some or all of plaintiffs' claims being preempted by federal law. As such, the Court declines to strike defendants' thirty-second affirmative defense. Plaintiffs' motion to strike is **denied** with respect to the thirty-second affirmative defense.

I. Thirty-Seventh Affirmative Defense

Defendants' thirty-seventh affirmative defense states as follows: "Plaintiffs' claims are barred, in whole or in part, because the promotion of the products at issue is protected by the First Amendment of the United States Constitution and similar provisions in applicable State constitutions." (Doc. 8, at 57). Plaintiffs argue that the affirmative defense should be stricken as immaterial and impertinent because "[t]his is not a defamation action," and "the First Amendment does not shield [d]efendants from injuring [p]laintiff[s]." (Doc. 14, at 15).

The parties have not given the Court complete context as to the bases for their arguments, which leaves the Court at a disadvantage in assessing the merits of the parties' arguments. To the best of the Court's understanding, defendants intend to argue that certain statements defendants made in promoting the allegedly defective hip joint were true and non-misleading at the time those statements were made and that, as a result, defendants had a First Amendment right to make those statements. (*See* Doc. 243, at 22-23).

In the regulatory context, at least, the government has less authority to regulate commercial speech if the speech is not misleading. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 477 U.S. 557, 564 (1980). Defendants' arguments in resisting plaintiffs' motion indicate that defendants intend to advance an argument that the *Central Hudson* test applies in this case as well. The Court does not have enough information to evaluate the merits of this perceived argument, nor does the Court have enough information to evaluate the merits of plaintiffs' motion to strike this affirmative

defense. The Court does, however, recognize a potentially cognizable argument in defendants' pleadings, and the Court is unwilling to take the drastic step of striking defendants' First Amendment affirmative defense in light of the potentially valid argument. Plaintiffs' motion to strike is, therefore, **denied** as to the thirty-seventh affirmative defense.

IV. CONCLUSION

For the aforementioned reasons, plaintiffs' motion to strike (Doc. 13) is **granted in part, denied in part, and denied as moot in part**. To the extent defendants have moved for leave to amend their thirty-fourth and thirty-eighth affirmative defenses, such motion is **denied**.

IT IS SO ORDERED this 28th day of January, 2019.



C.J. Williams
United States District Judge
Northern District of Iowa